

Wildlife and Countryside Link response to ‘the regulation of genetic technologies’
consultation, March 2021

Introduction

The use of gene editing technology raises ethical and scientific questions that merit a serious public debate. This consultation seeks to pre-empt such a debate, by appearing to favour a particular outcome and to invite endorsement of a deregulatory approach. It offers little analysis of the ethical, animal welfare and ecological questions raised by the use of gene editing. It does not assess the real need for the technology, nor does it support a meaningful process for a review of scientific evidence and public debate.

Crucially it does not consider alternative options—such as agroecological farming, improved animal husbandry and integrated pest management—which could improve whole farming systems and tackle the root causes of environmental and productivity problems, rather than just treat the symptoms as gene editing seems to seek to do.

The consultation also does not set out an alternative proposal for a new regulatory approach to gene editing, were the current restrictions to be relaxed. It also fails to take a precautionary approach, or acknowledge the importance of the precautionary principle for regulating all novel gene editing technologies, as it only references its importance for GMOs produced through transgenesis. The purely deregulatory change this implies would not be a proportionate approach. The proposals may also breach the non-regression duty in the Trade & Cooperation Agreement with the EU on the basis that they appear to amount to a lowering of the standard of environmental protection in a way which may impact on trade and investment (eg: by attracting gene editing business to the UK).

To remedy these omissions, a further consultation should take place, to allow for full discussion of the distinct ethical and animal welfare concerns arising from gene editing of sentient animals, and the potential environmental impacts of gene edited crops and other plant organisms. It should also set out a clear proposal for any future regulatory framework, should the current rules be amended.

Rather than addressing the questions of this consultation directly, we outline each of our key concerns in more detail below, to further highlight the need for a fuller and more adequate consultation process and a precautionary approach.

Lack of Clarity on the Scope and Purpose of the Consultation

The scope and purpose of this consultation are not sufficiently clear and explicit.

GE technologies have increasingly broad relevance across many fields, with multiple and distinct uses and potential applications being identified. Each has its own unique context, with different risks, benefits, regulation and impacts. For instance, the potential use of GE technology and gene drives for the control of invasive non-native species (INNS) is currently being explored internationally. The technology might promise significant gains in terms of welfare and technical feasibility of INNS control, but it simultaneously brings a series of potentially severe environmental risks, which are the subject of much active debate among the scientific and conservation communities.

However, it is unclear whether this application of GE (among others) would be within the scope of this consultation. In Part 1, it is suggested that the main purpose for a change in regulation for GE is

intended for farming and animal husbandry, however this it is still not made explicit, and there is opportunity to include GE for INNS control-and other uses- into the box on p.11 under 'other sectors/activities'. Within Part 2, again it is not clear whether these uses are within scope.

This is just one example of where the consultation is inadequately defined and explained, as it fails to take explicit account of the specific intended purposes and implications of any changes to regulation around GE. We are concerned that this shortcoming may result at best in the need for multiple, further, more specific consultations and at worst in the development of inadequate regulation in the face of diverse societal and environmental risks and unintended impacts.

Traditional breeding methods Vs Gene Editing

The consultation suggests that GE organisms' "genetic change(s) could have been produced by traditional breeding", implying that traditional breeding and GE will produce the same results and, in the case of animals, have the same impact on welfare. This is potentially misleading because there is no conclusive evidence presented in the consultation to suggest that genetic changes made to an organism through GE will necessarily produce results that could be achieved through traditional breeding.

The implications of deregulating GE are potentially extremely widespread, and affect a wide variety of stakeholders, from farmers and other land managers, to food businesses and the general public. The environmental implications are also little known, but again the impacts could be significant. The scope and framing of this consultation do not account for the complexities involved.

Animal welfare

The consultation suggests that animal welfare improvements could be achieved through gene editing. While this may be the outcome in some cases, significant animal welfare and ethical concerns need to be addressed before GE proposals progress, and there are alternative approaches to improving farm animal health and welfare that do not necessitate editing the genomes of sentient animals. A number of precedents suggest that productivity-focussed genetic interventions via traditional selective breeding lead to animal suffering.

For example, high rates of osteoporosis amongst broiler chickens¹ are partially the result of selection designed to increase egg-laying productivity, regardless of animal welfare consequences. Fernyhough et al's 2019 paper 'The Ethics of Laying Hen Genetics' sets out how 'selective breeding for productivity traits means that the calcium required for egg shell production is greater than the medullary bone can supply; structural bone becomes utilised in egg shell production and subsequently bones become osteoporotic, resulting in bone fragility'.²

Traditional selective breeding has indeed produced extreme traits that cause welfare issues, and there is little to suggest that GE technology would not do the same.

It is expected that future GE for farmed animals will be similarly profit-focused. The Nuffield Council's 2016 ethical review of genome editing considered ongoing GE to reduce disease risks amongst farmed animals and noted, 'If this risk were reduced or removed altogether then it might be easier to pack more animals together in crowded spaces. Not necessarily a win for proponents of animal welfare.'

¹ <https://pubmed.ncbi.nlm.nih.gov/10901207/>

² <https://link.springer.com/article/10.1007/s10806-019-09810-2>

Something similar might apply to hornless cows or tailless pigs, where head butting or tail biting might otherwise be addressed by providing more space for cows or more straw for pigs'.³

GE cannot be a means of partially addressing animal health or welfare problems, when it creates new ones. This full impacts of GE on animal welfare, including harms to individual used to create new GE lines, must be explored in more detail.

Public choice and consultation

This should be a time for wide and properly informed public debate about the future direction of food and farming, and the role of innovation and technology in a transition to a more sustainable food and farming system. We are concerned that rather than stimulating public engagement and discussion, this consultation is simply a statement of intent for Government to deregulate gene-editing techniques. This could lead to entrenchment and polarisation of views, rather than a balanced debate. A wider, more considered and structured consultation is needed over a period of time. This would be in keeping with the aspirations set out in the Government's Health and Harmony consultation⁴.

A more inclusive public discussion around the regulation of GE should start with a clear exposition of the current situation and the perceived problem, and a balanced and independent consideration of the science and risks. Such an approach would benefit from being UK-wide, and looking at social and ethical issues as well as economic and trade dimensions. The approach should learn from the points made about democratising innovation in the 2014 Chief Government Scientist report⁵, which looked at GE as a key case study. It could also be modelled on the Nuffield Council on Bioethics' ongoing public dialogue project⁶.

Knowledge gaps

Gaps in scientific evidence for GE impacts on the wider environmental, animal welfare and human health warrant a precautionary approach to regulation.

Below we list a small selection of examples of significant knowledge gaps about GE employing gene drive technology and its environmental impact:

- **Proof-of-concept studies:** These are extremely limited in the GE of gene drives, being restricted (until the recent lab mouse report⁷ in 'Nature') at present to yeast, two species of mosquito and fruit flies - all fast-reproducing laboratory organisms.
- **Resistance:** Malaria-focused research⁸ on gene drives in mosquitos has found that individuals resistant to the inserted gene drives arose in laboratory populations, and concluded that insects with the resistance mutation are likely to flourish. This or similar genetic effects in host populations could mean the technology simply will not work in wild populations.
- **Horizontal gene transfer:** Genetic material can sometimes be transferred (e.g. by viruses) between a target species and entirely different species, incorporated in genomes and genes

³ <https://www.nuffieldbioethics.org/publications/genome-editing-an-ethical-review>

⁴ <https://www.gov.uk/government/consultations/the-future-for-food-farming-and-the-environment>

⁵ [2014 Chief Government Scientist report](#)

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⁷ <https://www.nature.com/articles/d41586-019-00185-y>

expressed in phenotypes. Such events may be rare – but with gene drives being designed to cause, and potentially inducing in reality, the complete extinction of a target population, the potential impacts of any horizontal transfer could be disastrous. However, there is little current empirical knowledge available on how, when and where this might occur.

- **Intrinsic factors in target populations:** There are significant knowledge gaps on: the evolutionary fitness (ability to reproduce fertile offspring); ‘conversion rates’ (how genes move between generations); gene flow (how genes move between populations), with respect to potential target populations.
- **Self-exhausting gene drives:** at present, understanding of how gene drives designed to be ‘self-exhausting’ would behave in wild populations is inadequate.
- **Reversibility:** techniques to reverse the effects of self-propagating gene drives – including the introduction of new gene drives to counteract previously inserted ones – are at present almost completely untested.

The question of whether GE can faithfully replicate natural processes is key to the public policy question of whether GE should be treated differently from genetic modification in law. The consultation does not adequately substantiate its main premise: that gene editing is different from genetic modification. The ruling of the ECJ in 2018 stipulates that by definition GE organisms are GMO because they are lab-based genetic engineering processes which are “new techniques of mutagenesis” or “directed mutagenesis” and which produce novel genetically modified organisms⁹. This was based on a robust two-year review of scientific evidence. To the contrary, there has been no such review carried out by UK regulators to present the evidence available on GE. Such a review is needed to inform the proposals advanced by this consultation.

Trade and devolved nations

With between 60-65% of the UK’s agricultural exports going to the EU, deregulating GE would create issues for farmers and producers currently exporting their goods to this important market, given the rules that apply in the EU around GM foods.

Although GE regulation is devolved, so can be approved in England, the internal trade in GE products is not devolved. Under the Internal Market Act 2020, Governments in Scotland and Wales have very limited powers to stop the internal trade in a product from another GB country, or even to discriminate against the import of products with labelling. Under the non-discrimination principle (Article 5), any good produced in one part of the UK must be able to ‘travel’ to another part of the UK and cannot be placed at a commercial disadvantage (Article 8). In essence, this means the options for the Welsh or Scottish Governments to not allow the sale of GE products, or even provide consumer information on these, are almost non-existent.

A Government in Wales or Scotland which did not permit the production or marketing of food from GE animals could still be mandated to allow these for sale without mandatory labelling, if there is no labelling of that product in England. As Northern Ireland is within the EU’s single Market and Customs Union, production, import and sale of GE products are illegal, so imported GE products would not be permitted. Regulations are yet to be laid under the Internal Market Act 2020, so it is unclear how those provisions will apply to GB-Northern Ireland trade.

⁹ <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

Conclusion

The apparent drive to deregulate this important area, so soon after Brexit, threatens to undermine confidence in this government's stated aims to have the highest global environmental standards and to safeguard animal welfare. Editing the genes of living animals and plants is human intervention in the natural world at its most literal and requires close examinations of motivations and desired outcomes. This consultation fails to deliver such examination.

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This response is supported by the following Link members:

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